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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,993	06/27/2001	Kelly R. Brown	ETH-1567	3764
27614	7590	08/10/2007	EXAMINER	
MCCARTER & ENGLISH, LLP			FUBARA, BLESSING M	
FOUR GATEWAY CENTER			ART UNIT	PAPER NUMBER
100 MULBERRY STREET			1618	
NEWARK, NJ 07102				
MAIL DATE		DELIVERY MODE		
08/10/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/892,993	BROWN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 30 April 2007.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

- 4)  Claim(s) 26-33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 26-33 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_ .  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_ .

## **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 10/10/2006. New claim 33 is added. Claims 26-28 are amended. Claims 26-33 are pending.

***Previous rejections and objections that are not reiterated herein are withdrawn.***

### ***Response to Amendment to the Specification***

Amendment to the specification is not entered because the amendment is adding to the specification more than what is originally disclosed by way of the drawings. For example, disclosing that the “discrete layer of the porous ceramic phase is positioned on the top of the interphase region, ...on the bottom of the interphase region” appears to be adding more than what is originally disclosed. Hence, amendment to the specification is not entered.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 26-28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. (“Evaluation of multiphase implants for repair of focal osteochondral defects in goats,” in Biomaterials, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000, cited in applicant’s specification at paragraph [0008] of the published application).

Niederauer describes the use of biodegradable multiphase scaffold for repair of articular cartilage (abstract); the multiphase scaffold comprises polymer and ceramic phases (Table 1 and 3<sup>rd</sup> and 4<sup>th</sup> full paragraphs, left column of page 2563) meeting the claimed scaffold having a ceramic and polymer phase; the phases are glued together using a solvent (page 2563, first three lines of text in right column) representing the discrete phases of scaffold of the claims and also meets claim 33; boring a receptacle space at the gradient junction of the site of injury as recited in claim 26-28 read on the experimental design of Niederauer where defect sites are made in the right and left stifles and bilateral arthrotomies performed to place the implants (paragraph 2.4 at page 2564); the scaffold is implanted into the prepared knees. Niederauer does is silent on placing the ceramic phase next to the bony tissue and placing the polymer phase next to the cartilage tissue. However, it is known in the art that ceramics closely resemble constituents of natural bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Niederauer to repair articular cartilage by placing the ceramic phase of the scaffold next to the bony tissue since the ceramic material closely resembles the bony tissue so that the bony tissue would grow into the ceramic tissue during the repair process.

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4. Claims 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. ("Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in *Biomaterials*, Vol. 21, Issue 24, pp 2561-2574, 15 Dec. 2000, cited in applicant's specification at paragraph [0008] of the published application) in view of Vyakarnam et al. (US 6,306,424).

Niederauer is discussed above for rendering *prima facie* obvious claims 26-28 and 33.

While Niederauer describes a scaffold that is made up of porous polymer phase and porous ceramic phase, Niederauer does not describe any of the porous phases as foamed material. However it is known to use porous and foamed scaffold for repair or regeneration of tissues as taught in Vyakarnam (column 1, lines 17-21 and Title) and the porous structures are formed by lyophilization (column 4, lines 11-24). The foamed scaffold meets the limitation of claim 29; lyophilization to make foamed structure meets claims 30-32. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form porous foamed scaffold structure by lyophilization with the expectation of obtaining organization at the microstructural level that facilitates tissue repair/regeneration.

No claim is allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

(BF)



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER